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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,223	MANGIARDI ET AL.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *25-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24 and 37-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07112003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-24 and 37-42, in the reply filed on February 7, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 25-36 have been withdrawn from consideration.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "410" as included in Figure 10; "400" as included in Figure 18; and "120" as included in Figures 27 and 28. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "100" as mentioned at page 8, lines 15 and 16, and page 9, line 25. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:

a. At page 6, line 16, --configuration-- apparently should be inserted following "uninflated".

b. At page 6, line 29, --configuration-- apparently should be inserted following "inflated".

c. At page 9, line 8, "230" apparently should read --240--.

d. At page 10, line 29, "280, 330" apparently should read --290, 340--.

e. At page 11, line 5, "mechanisms" apparently should read --mechanism--.

f. At page 11, line 29, "480" apparently should read --470--.

g. At page 12, line 2, the first occurrence of "diameter measurement" apparently should

be deleted.

Appropriate correction is required.

5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

6. Claim 15 is objected to because of the following informalities: in line 4, "mechanism" apparently should read --assembly--. Appropriate correction is required.

7. Claim 17 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 17 is substantially identical to claim 8.

8. Claim 20 is objected to because of the following informalities: in line 2, "mechanism" apparently should read --assembly--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 3-6, 10-13, and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "the first conduit" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no “first conduit” recited in the claims prior to this recitation, and one cannot be certain whether this limitation is intended to refer to the interior or exterior conduit.

Regarding claim 5, the claim language renders the claim indefinite, as one cannot be certain what the limitation “thereof”, as recited in line 3, is intended to refer to.

Claim 6 recites the limitation "the first and second handle locations" in line 4. There is insufficient antecedent basis for this limitation in the claim. There are no “first and second handle locations” recited in the claims prior to this recitation.

Claim 10 recites the limitation "the first conduit" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no “first conduit” recited in the claims prior to this recitation, and one cannot be certain whether this limitation is intended to refer to the interior or exterior conduit.

Regarding claim 12, the claim language renders the claim indefinite, as one cannot be certain what the limitation “thereof”, as recited in line 3, is intended to refer to.

Claim 13 recites the limitation "the first and second handle locations" in line 4. There is insufficient antecedent basis for this limitation in the claim. There are no “first and second handle locations” recited in the claims prior to this recitation.

Claim 39 recites the limitation "the first conduit" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no "first conduit" recited in the claims prior to this recitation, and one cannot be certain whether this limitation is intended to refer to the interior or exterior conduit.

Regarding claim 41, the claim language renders the claim indefinite, as one cannot be certain what the limitation "thereof", as recited in line 3, is intended to refer to.

Claim 42 recites the limitation "the first and second handle locations" in line 4. There is insufficient antecedent basis for this limitation in the claim. There are no "first and second handle locations" recited in the claims prior to this recitation.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-3, 6-10, 13, 37-39 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Matthews et al. ('351). Matthews et al. teach a measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device

(110) includes an exterior conduit (120) having measurement markers (152) formed on a portion thereof; an interior conduit (130) slidably disposed within the exterior conduit and having a depth marking mechanism (132) which may be visible through a portion of the exterior conduit (col. 6, lines 9-11); a measurement assembly including a plurality (two) of legs (140, 142) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (136, 138, 139) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration. The inward facing surfaces along a portion of the legs are substantially flush with one another when the measurement assembly is closed. The legs form an acute angle (150) with respect to one another as the measurement assembly is moved distally in relation to the first conduit. The handle further includes a measurement indicator (edge of opening (134), wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between the first and second handle locations. The device is used to measure a target segment of a lumen in the knee of a patient so as to select a suitable interventional prosthesis. In operations the device is introduced into an appropriate anatomical orifice of a patient; delivered adjacent a target segment of a lumen within the patient; and the length of the target segment is measured within the patient. An optical scope may be operatively coupled therewith (col. 3, lines 21-23), so that the measuring step may be accomplished using the optical scope.

13. Claims 1-4, 6-11, 13-23, 37-39 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Colvin et al. ('892). Colvin et al. teach a body lumen measuring device that is

capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (10) includes an exterior conduit (12) having measurement markers (24) formed on a portion thereof; an interior conduit (16) slidably disposed within the exterior conduit and having a depth marking mechanism (22) which may be visible through a portion of the exterior conduit (20); a measurement assembly including a plurality of legs (54a-54c) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (14) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly (18) by actuating the handle along a continuum between a first closed configuration and a second open configuration. The inward facing surfaces along a portion of the legs are substantially flush with one another when the measurement assembly is closed. The legs form an acute angle with respect to one another as the measurement assembly is moved distally in relation to the first conduit. The handle further includes the measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between the first and second handle locations. The device is used to measure a target segment of a lumen of a patient so as to select a suitable interventional prosthesis. In operations the device is introduced into an appropriate anatomical orifice of a patient; delivered adjacent a target segment of a lumen within the patient; and the length of the target segment is measured within the patient. An optical endoscope may be operatively coupled therewith, so that the measuring step may be accomplished using the optical endoscope. The device may be used to measure the diameter and length of a stenotic

target segment of the lumen within the patient, including the height and length of the stenosis.

14. Claims 1, 5-7, 12-14, 16-23, 37, 41 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Korotko et al. ('976). Korotko et al. teach a body lumen measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (Figs. 7-12) includes an exterior conduit (112) having measurement markers (118, 144) formed on a portion thereof; an interior conduit (110) displaceably disposed within the exterior conduit and having a depth marking mechanism (120, 142) which may be visible through a portion of the exterior conduit; a measurement assembly including a plurality of legs (130) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (134) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration. The distal ends of the legs are coupled together by the exterior conduit and measurement of the target site takes place between the proximal and distal ends of the legs. The handle further includes the measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between the first and second handle locations. The device is used to measure a target segment of a lumen of a patient so as to select a suitable interventional prosthesis. In operations the device is introduced into an appropriate anatomical orifice of a patient; delivered adjacent a target segment of a lumen within the patient; and the length of the target segment is measured within the patient. The

device may be used to measure the diameter and length of a stenotic target segment of the lumen within the patient, including the height and length of the stenosis.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 24 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin et al. ('892) in view of Jain ('147). Colvin et al., as discussed above, teach all of the limitations of the claims except that the measurement assembly includes four legs. Jain teaches a vessel measuring device including an exterior conduit (22), an interior conduit (24), and a measurement assembly including four or more legs (44, see Figure 3). Applicant has not disclosed that using a measurement assembly having four legs solves any stated problem or is for any particular purpose. Moreover, it appears that the measurement assembly of Colvin et al. would perform equally well with the four legs, rather than two or three legs. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Colvin et al., to include a measurement assembly having four or more legs, similar to that of Jain, because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Colvin et al.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kurz ('548) teaches a sound for insertion into the body for the determination of internal measurements of hollow organs. King et al. ('867) teach a uterine caliper and depth gauge. Doi ('359) teaches an endoscopic length measuring tool. Zeppelin ('863) and Zeppelin ('633) teach medical instruments for measuring the interior of the womb.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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February 15, 2005